K101712

510(k) Summary
Endo Laser Vein System Kit with Radial Fiber

OCT 27 2010

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
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Contact Person: Harry Hayes, Ph.D. – Regulatory Consultant
Date prepared: June 7, 2010

Name of Device and Name/Address of Sponsor

Endo Laser Vein System Kit (ELVeS®) with Radial Fiber
Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Surgical laser accessories

Predicate Devices

Ceralas D Diode Laser System (1470nm, 980 nm and 810 nm) with ELVeS Kit

Intended Use/Indication for Use

The device is intended for endovascular coagulation of blood vessels. The device is indicated for the endovascular coagulation of the greater saphenous vein in the thigh in patients with superficial vein reflux.

Technological Characteristics

The ELVeS kit with Radial Fibers contain the following components: (1) radial fiber; (2) access needle; (3) introducer sheath/ dilator; and (4) a guidewire.

Performance Data

The device complies with the following voluntary consensus standards: 21 C.F.R. §§ 1040.10 & 1040.11; ANSI/AAMI ES1; IEC 601-1; IEC 601-2-22; EN 60825-1, and ANSI/AAMI/ISO 10993-7.

Substantial Equivalence

The ELVes with Radial Fiber uses previously cleared radial fiber technology (K924258) and has the same intended use and indications for use as the cleared Ceralas D 1470, 980 and 810nm ELVeS kits. The ELVeS kit is not a new technological characteristic for diode lasers for endovascular coagulation of the greater saphenous vein in the thigh in patients with superficial vein reflux. Thus, the ELVeS is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biolitec, Inc.
% Genmarhay BDA
Mr. Harry Hayes
1349 Main Road
Granville, Massachusetts 01034

OCT 27 2010

Re: K101712
Trade/Device Name: Endo Laser Vein System Kit with Radial Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 12, 2010
Received: October 13, 2010

Dear Mr. Hayes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101712

OCT 27 2010

Device Name: **Endo Laser Vein System Kit with Radial Fiber**

For endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __√__ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

Neil R Ogden for mrm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101712